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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,531	02/07/2005	Satoru Oi	2005_0168A	3706
513 7590 08/11/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
EXAMINER				
SOLOLA, TAOFTQ A				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
08/11/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/523,531

Applicant(s)

OI ET AL.

Examiner

Taofiq A. Solola

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 4/10/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-21, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 17-21, 27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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The Office action supersedes the last communication.

Claims 1-21, 27-28 are pending in this application.

Claims 22-26 are deleted.

Claims 17-21, 27-28 are non-elected.

Response to Restriction

The election of group XII, claims 1-16, in the Paper filed 1/31/08, is hereby acknowledged. Applicant also elects example 19. There is no indication if the election is made with traverse or not. Therefore, it is deemed made without traverse. Claims 1-16, are being examined in part according to applicant's election.

The requirement is still deemed proper and therefore made FINAL.

Claim Rejections - 35 USC § 112

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims lack adequate support in the specification. It is not possible to determine the structures of the compounds that are included and/or excluded by "hydrocarbon group" or "prodrug". Hydrocarbon embraces the entire textbook of organic chemistry. The term is defined in the specification by examples. However, "[e]xemplification is not an explicit definition." The specification must set forth the definition explicitly and clearly, with reasonable clarity,

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deliberateness and precision, *Teleflex Inc. v. Ficosa North Am Corp.*, 63 USPQ2d 1374, (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1854 (Fed. Cir. 2001).

The term "prophylactic", claims 11-14, implies prevention but the specification fails to disclose how people predispose to diabetes would be identified and treated before the occurrence of the disease. Also, the term "diabetes" embraces type I diabetes, a genetic disease, which is not preventable. By deleting the term the rejection would be overcome.

Claims 15-16 are drawn to mechanism: peptidase inhibition. This is not a practical utility under the US patent practice. To ascertain the practical utilities, one must read the specification into the claims contrary to several precedent decisions by the US courts and Official practice. The claims are attempts by applicant to claim treatment of all diseases known today and that may be discovered in the future, arising from the mechanism. They are reach-through claims and are no longer patentable under the US patent practice. A claim must stand alone to define the invention, and incorporation into the claims by reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993). By deleting the claims the rejection would be overcome.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite. It is not possible to determine the structures of the compounds that are included and/or excluded by "hydrocarbon group" or "prodrug". Therefore, it is not possible to ascertain the metes and bounds of the claims.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakurai et al., Bull. Chem. Soc. Japan, (1969), Vol. 42(1), pp. 220-3.

Sakurai et al., disclose the compound in the abstract, which is presumed to be a prodrug of the instant compounds absent a showing to the contrary.

Objection

Claims 1-16 are objected to for containing non-elected subject matter. The subject matters of the elected invention are allowable over prior arts of record, and claims 1-16 must be amended accordingly.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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/Taofiq A. Solola/

Primary Examiner, Art Unit 1625

August 5, 2008